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07/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.  
**09/282,879**

Applicant(s)

**Chatterjee et al.**

Examiner  
**Manjunath N. Rao**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Apr 27, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 13-30 is/are pending in the application

4a) Of the above, claim(s) 18-30 is/are withdrawn from consideration

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 13-17 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Claims 13-30 are still pending in this application. Claims 13-17 are now under consideration. Claims 18-30 remain withdrawn from consideration as being drawn to non-elected invention.
2. Applicants' arguments filed on 4-27-01, paper No. 7, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying a compound useful in the diagnosis or treatment of a human neutral sphingomyelinase related disorder comprising contacting a candidate pharmacological agent with native human sphingomyelinase, does not reasonably provide enablement for an identical method of identifying a compound comprising the use of any fragment or any derivative of human neutral sphingomyelinase. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In response to the previous Office action, applicants have traversed the above rejection. Applicants argue that the rejection under 35 U.S.C. §112, first paragraph is not proper because the specification defines fragments and derivatives of sphingomyelinase as those that do retain the sphingomyelinase activity. Examiner acknowledges that such a definition is provided in the specification it is still not persuasive to overcome the above rejection because the definition is limited only to activity and there is no information regarding the structure of the derivative or the fragment. The definitions are still too broad. For example any compound or a stretch of an amino acid sequence even unrelated to SEQ ID NO:2 with sphingomyelinase activity is encompassed in the claim. The point Examiner is trying to make is that the claim is so broad that fragments or derivatives which are unrelated to human neutral sphingomyelinase in terms of either homology to the nucleic acid encoding the human neutral sphingomyelinase or amino acid sequence of human neutral sphingomyelinase are still encompassed in the claim. Amending the claim to show that the fragments and derivatives are derived from the amino acid sequence with SEQ ID NO:2 would overcome this rejection.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (J. Biol. Chem., 1989, Vol. 264(21):12554-12561) and Ogita et al. (WO 9518119, 7-6-1995) in view of the high level of knowledge in the art. See previous Office action for rejection.

In response to the previous Office action, applicants have traversed the above rejection of claims 13-17 by amending claim 13 to recite "recombinant human neutral sphingomyelinase" and also arguing that none of the references taken individually or in combination provide for use of such an enzyme in any assay and that in contrast, the claimed invention features recombinant enzyme for use in assays to detect agents which modulate the activity of the above enzyme. Examiner respectfully disagrees. The above argument and amendment is still not persuasive to overcome the rejection because even though both the above references do not teach recombinant sphingomyelinase, the reference of Chatterjee et al. does teach the purification of the enzyme. Applicants have not shown that the recombinant enzyme differs in any material respect from the enzyme purified by Chatterjee et al. Furthermore, it would have been obvious to one of ordinary skill in the art to obtain the partial amino acid sequence of the purified enzyme and clone the gene encoding the above enzyme and make recombinant form of the enzyme for use in such assays. Applicants also argue that Ogita et al. reference discloses sphingomyelinase inhibitors and not inhibitors of neutral sphingomyelinase of the instant application. While this may be so, Examiner relied on the above reference as nowhere in the reference there is a disclosure that the

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inhibitors do not act on neutral sphingomyelinase. In view of this, Examiner believes that Ogita et al. reference includes inhibitors for all sphingomyelinases including neutral sphingomyelinase. Therefore, both the above references render claims 13-17 *prima facie* obvious.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

#### ***Conclusion***

4. No claims are allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao. Ph.D.  
July 12, 2001

*Rebecca Prouty*  
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PRIMARY EXAMINER  
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